DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 27, 2015

Sun Medical Co., Ltd.
c/o Ms. Carrie Hetrick
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K150511
Trade/Device Name: Coating Material
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: February 26, 2015
Received: February 27, 2015

Dear Ms. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150511

Device Name
Coating Material

Indications for Use *(Describe)*
Coating Material is a light-cured, transparent resin sealant for acrylic denture bases that produces a smooth, glossy surface finish on the denture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

for

Coating Material

1. Submission Sponsor

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3. Date Prepared

May 19, 2015

4. Device Identification

Trade/Proprietary Name:	Coating Material
Common/Usual Name:	Coating Material
Classification Name:	Denture Relining, Repairing, or Rebasing Resin
Classification Regulation:	21 CFR § 872.3760
Product Code:	EBI
Device Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate Device(s)

Heraeus Kulzer, Inc., Palaseal® - K892452

6. Device Description

Coating Material is a light-cured denture base coating that is composed of two liquids that are mixed prior to use, and then photo-polymerized by a UV light. The coated surface

provides smoothness and glossiness to the surface of an acrylic denture base. The coated layer is transparent, so it does not affect the original color of the denture.

7. Indication for Use Statement

Coating Material is a light-cured, transparent resin sealant for acrylic denture bases that produces a smooth, glossy surface finish on the denture.

8. Substantial Equivalence Discussion

The following table compares the Coating Material to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Sun Medical Co., Ltd.**	**Heraeus Kulzer, Inc.**	**Significant Differences**
Trade Name	**Coating Material**	**Palaseal®**	
510(k) Number	K150511	K892452	Not applicable
Product Code	EBI	EBI	Same
Regulation Number	21 CFR § 872.3760	21 CFR § 872.3760	Same
Regulation Name	Denture Base Resin	Denture Base Resin	Same
Device Description	Coating Material is a light-cured denture base coating that is composed of two liquids that are mixed prior to use, and then photo-polymerized by a UV radiation.	Palaseal® is a light-curing, transparent sealing resin that bonds to any denture materials, temporary crowns, and bridges. The patient receives an aesthetically and functionally comfortable denture.	Similar with minor variation - Both are transparent, light-cured resins intended to seal acrylic dentures
Indications for Use	Coating Material is a light-cured, transparent resin sealant for acrylic denture bases that produces a smooth, glossy, and functionally comfortable denture.	Photocuring lacquer for sealing dentures and temporary crowns and bridges based on PMMA-resin.	Similar with minor variation- both are a coating material for dentures. The predicate is also intended for use in temporary crowns and bridges.
Area of application	- Surface sealing of dentures - Surface sealing of dentures after finishing	- Surface sealing of dentures - Surface sealing of dentures after finishing - Surface sealing of temporary crowns and bridges	Similar with minor variation – both are intended for sealing dentures. They differ in that the Palaseal is also intended to be used as a surface sealant of temporary crowns and bridges
Chemical composition	Acrylic compounds, solvent, and a photo initiator	Multifunctional methacrylate, methyl methacrylate, and a photo initiator	Similar - The devices are composed of similar acrylic raw materials, have the same intended use and technological

Manufacturer	Sun Medical Co., Ltd.	Heraeus Kulzer, Inc.	Significant Differences
			characteristics.
Polymerization (Curing) Method	Cured by Ultraviolet (UV) radiation	Cured by Ultraviolet (UV) radiation	Same
Components	Two-Component System - Liquid A and Liquid B	One-component System - Denture Lacquer	Differ - The subject device is a two-part liquid system that requires the user to mix, and the predicate is one part liquid system.
Appearance	Smooth, high gloss surface with no evidence of cracking or peeling after being light-cured	Smooth, high gloss surface with no evidence of cracking or peeling after being light-cured	Same
Application	Applied with a brush or by dipping into a tub	Applied with a brush	Similar - Both may be applied with a brush
Biocompatibility	ISO 10993-1, ISO 7405	ISO 10993-1, ISO 7405	Same

The subject and predicate devices are liquid formulations that contain acrylic compounds, solvent, and an initiator. All of the components of the Coating Material have similar to the predicate device. Coating Material requires the user to mix the two liquid components, while the predicate is a one-liquid product. The curing mechanism of the devices is polymerization of uncured acrylic monomers. This reaction is caused by a photo initiator system.

The Coating Material shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device. All of the components have been used in legally marketed devices. The formulations have not been changed in ways that may adversely impact device performance.

9. Non-Clinical Performance Data

Extensive testing has been performed on the subject denture base resin to demonstrate compliance with *ISO 7405:1997 Dentistry; Preclinical evaluation of biocompatibility of medical devices used in dentistry, Test methods for dental materials*. The following testing has been performed to support substantial equivalence:

Biocompatibility –The biological safety of the Coating Material was evaluated in accordance with *ISO 7405:2008, ISO 10993-1: 2009* and guidance document entitled *Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing.* Under these, for the stated indications for use, the device was classified as a permanent exposure (C), surface-contacting device in contact with mucosal membranes. The Coating Material biocompatibility was tested for the following with the final results.

- Cytotoxicity (MEM Elution Test) – The Coating Material was found to be non-cytotoxic, and all test method acceptance criteria were met per ISO 10993-5.
- Skin Sensitisation (Guinea Pig Maximization) - Coating Material is considered to cause no sensitization under the experimental conditions of this study per ISO 10993-10.

- Intracutaneous Reactivity - Coating Material caused no signs of irritation, met the requirements of the test and is classified as not irritant per ISO 10993-10.
- Subchronic Toxicity - Coating Material is considered to not cause significant systemic toxicity under the experimental conditions of this study per ISO 10993-11.
- Genotoxicity (In Vitro Mammalian Chromosome Aberration Test) - Coating Material extract is considered to be non-clastogenic under the experimental conditions of this study per ISO 10993-3.
- Genotoxicity Bacterial Reverse Mutation (AMES) Test - Coating Material was considered non-mutagenic (non-genotoxic and non-clastogenic) under the experimental conditions of this study per ISO 10993-3.

Performance Bench Testing – It is confirmed that the Coating Material conforms to the required specifications and is suitable for its intended use. Performance testing includes:

- Coating applicability
- The properties of the coated surface

Risk Management – Risk Analysis was conducted according to ISO 14971, and the outcomes of these risks are considered acceptable, and that all potential risks have been mitigated to the lowest form.

The Coating Material meets all the requirements for the overall design, performance, and biocompatibility, confirming that the output meets the design inputs and specifications. The Coating Material passed all testing stated above as shown by the acceptable results obtained.

The Coating Material complies with the applicable voluntary standards for biocompatibility. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years and there are no adverse reactions. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

The Coating Material has the same or similar intended use, indications, principles of operation, and technological characteristics as the predicate devices. Coating Material, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices in terms of intended use, design, materials, and function.